UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

WILLIAM W. REEVES,	)	Case No. 1: 11 CV 2347
	)	
Plaintiff,	)	JUDGE DONALD C. NUGENT
vs.	)	
	)	MEMORANDUM OPINION
PHARMAJET, INC.,	)	
	)	
Defendant.	)	

This matter is before the Court on Defendant's Motion to Dismiss and to Strike Class Allegations (ECF #7). For the reasons that follow, Defendant's Motion to Dismiss is granted.

PROCEDURAL AND FACTUAL BACKGROUND

Plaintiff William W. Reeves, brings this class action on behalf of himself:

> and all other persons similarly situated, throughout the United States, who are domociled in one of the fifty states, including Ohio, and who are consumers who received ANY vaccine or drug with a PharmaJet injector device where the specific vaccine or specific drug does not have the stated approval by the FDA for administration with a "needleless injector" or "needle-free injector," also know [sic] as "jet injectors".

(Complaint at ¶1.) Plaintiff avers that this Court has jurisdiction pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. §§ 1332(d) and 1453 because the proposed putative class exceeds 100, at least one plaintiff and one defendant are citizens of different states, Defendant PharmaJet is not a citizen of Ohio and the amount in controversy exceeds Five Million Dollars.

On October 11, 2011, Plaintiff went to the Giant Eagle Pharmacy in North Ridgeville Ohio to obtain a flu-shot. (Complaint, ¶6) The Pharmacy's health care provider administered a needle-free injection to the Plaintiff's upper arm without inquiring of Plaintiff as to whether he

would prefer a needle or needle-free injection. (Id. ¶8) Plaintiff asserts that he experienced swelling, redness and soreness at the site of the injection and was surprised to feel pain and see blood at the injection site because "he was told the injection device was "needle-less." (Id. ¶9). Further, Plaintiff avers that the needle-free injection administered to Plaintiff was provided by PharmaJet, "a company which manufactures and offers for sale a device and system to pharmacies and health care providers that effectuates the administration of needle-free injections." (Complaint, ¶10).

The Complaint sets forth a number of statements allegedly made by the Defendant about itself and its product which purportedly appeared on its website http://www.pharmajet.com/about.html. (Id. at ¶¶ 11-12). Specifically, Plaintiff alleges that PharmaJet's pronouncements, advertisements and marketing convey the distinct impression that PharmaJet's device and jet injection system is an FDA approved product and system for the administration of numerous vaccines and therapeutics in concert with its many listed applications. (Id. at ¶ 15)

On October 21, 2011, the United States Food and Drug Administration (FDA) issued a Communication on Use of Jet Injectors with Influenza Vaccines to health care professionals who administer influenza vaccines. The Communication is set forth in its entirety in the Complaint at paragraph 16. Essentially the Communication advises health care professionals not to use injector devices to administer influenza vaccines, and recommends that all vaccines, including influenza, be administered in accordance with their labeling. The FDA further noted that:

> * Currently, there is only one vaccine, measles, mumps and rubella (MMR), that is approved for administration by jet injector.
> * The FDA has no data to support the safety or effectiveness of

other vaccines delivered by jet injector.
* At this time, there are no vaccines for the prevention of influenza disease that are approved by the FDA for administration by jet injector.

On October 26, 2011, the FDA issued an Updated Communication on Use of Jet Injectors with Inactivated Influenza Vaccines. (See Complaint, ¶17 and ECF #7, Ex. A and B.)[1] The updated Communication reiterated the summary of the issue set forth in the October 21 Communication but further recommended that "[b]ased on limited information from recent publications using currently licensed inactivated influenza vaccines, FDA and the Centers for Disease Control and Prevention (CDC) believe that it is not necessary for people who received their influenza vaccine via jet injector to be re-vaccinated."

Plaintiff avers that these FDA Communications describe a required two step process to obtain FDA approval for the marketing, sale and use of any product for the administration of vaccines. First, the product and/or system must receive FDA approval as evidence by 510k statements, and the FDA must approve the specific vaccine to be administered through said FDA approved product and/or system. (Complaint, ¶18). The Complaint notes that Defendant presents two 510k statements on its website to assert the receipt of FDA clearance for the marketing and sale of its jet injector system, however, asserts that Defendant cannot show it

[1] While the Court's inquiry on a Motion to Dismiss brought under Rule 12(b)(6) is limited to the content of the Complaint, matters of public record, orders, items appearing in the record of the case, and exhibits attached to the Complaint may also be taken into account. *See Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008); *Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001). The Court may also take judicial notice of matters of public record including records of the FDA available on its website. *See In re Wellbutrin SR/Zyban Antitrust Litg.*, 281 F.Supp.2d 751, 754 n.2 (E.D. Pa. 2003); *Horne v. Novartis Pharm. Corp.*, 541 F.Supp.2d 768, 777 (W.D.N.C. 2008).

received FDA approval for the administration of influenza vaccines by means of its jet injector system. (Id. ¶23).

Based upon these averments, Plaintiff asserts one claim, that Defendant violates the Ohio Consumer Sales Practices Act ("CSPA"), Ohio. Rev. Code §1345, *et seq.* Specifically, Plaintiff asserts that PharmaJet violates the Ohio CSPA insofar as PharmaJet marketed and sold its jet injector device and system to healthcare professionals in Ohio and across the United States without having first received the approval of the FDA for the administration of the influenza vaccine by means of its jet injector device and system. Thus, the subject of PharmaJet's consumer transaction, the delivery of influenza vaccine to a consumer by means of PharmaJet's jet injector system, can never be of a particular standard, quality, or grade and is always based on a misrepresentation of PharmaJet's authority to provide the services it provides. (Complaint, ¶¶42-46)

Plaintiff alleges that Defendant's failure to submit specific data to the FDA to demonstrate the effectiveness of the flu vaccine, after administration with its needle-free injector has created a serious public health problem in that there is great uncertainty as to the effectiveness of a flu vaccine administered with a PharmaJet injector. As such, Plaintiff seeks the establishment of a national prospective clinical study of all people who received a flu shot via jet injection to determine the effectiveness of a PharmaJet flu vaccination. (Id. ¶¶67-86) Plaintiff also seeks compensatory damages, disgorgement of revenue earned in the United States from sales of its jet injector device, pre and post judgment interest and attorneys fees. (Id. at ¶¶87-89).

Defendant has moved to dismiss the complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6). Plaintiffs have filed a brief in opposition and Defendant has filed a reply brief

in support. The motion is now fully briefed and ready for decision.

STANDARD OF REVIEW

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) allows a defendant to test the legal sufficiency of a complaint without being subject to discovery. *See Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 566 (6th Cir. 2003). In evaluating a motion to dismiss, the court must construe the complaint in the light most favorable to the plaintiff, accept its factual allegations as true, and draw reasonable inferences in favor of the plaintiff. *See Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007). However, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitations of a cause of action's elements, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 129 S.Ct. 1937,1940 (2009). *See also Gregory v. Shelby County*, 220 F.3d 433, 446 (6th Cir. 2000) (court will not accept conclusions of law or unwarranted inferences cast in the form of factual allegations.)

In order to survive a motion to dismiss, a complaint must provide the grounds of the entitlement to relief, which requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is,"[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (internal citation omitted); *see Association of Cleveland Fire Fighters v. City of Cleveland*, No. 06-3823, 2007 WL 2768285, at *2 (6th Cir. Sept. 25, 2007) (recognizing that the Supreme Court "disavowed the oft-quoted Rule 12(b)(6) standard of *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed.2d 80 (1957)"). Accordingly, the claims set forth in a complaint must be plausible, rather than conceivable. *See Twombly*, 550 U.S. at 570.

On a motion brought under Rule 12(b)(6), the court's inquiry is limited to the content of the complaint, although matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint may also be taken into account. *See Bassett v. Nat'l Collegiate Athletic Ass'n,* 528 F.3d 426, 430 (6th Cir. 2008)*; Amini v. Oberlin College*, 259 F.3d 493, 502 (6th Cir. 2001).

DISCUSSION

Defendant asserts that Plaintiff's Complaint fails under both federal and Ohio law. First, Defendant contends that Plaintiff's claim is premised solely on alleged violations of the Food, Drug, and Cosmetic Act ("FDCA") and must fail because there is no private right of action for such a claim. Second, Plaintiff's attempt to state a claim under Ohio Consumer Sales Practices Act ("OCSPA") fails for lack of reliance and proximate cause, lack of a consumer transaction and because Defendant's device is not a good for "personal, household or family use." Third, Defendant asserts that Plaintiff cannot request medical monitoring under the OCSPA, especially given the FDA's statement that consumers need not be re-vaccinated. Finally, Defendant contends that Plaintiff's class allegations must be stricken because of the failings of Plaintiff's individual claims and for lack of notice. The Court will address each claim in turn.

1. Is Plaintiff's Claim Really One for an Alleged Violation of the FDCA?

As Defendant points out, Plaintiff's Complaint is replete with references to the FDA and actually reproduces one of the FDA's Communications verbatim. The basis of Plaintiff's entire claim is based on the FDA Communications and Plaintiff's conclusion from reading the Communications that Defendant failed to get a "Two-Step Approval" from the FDA before marketing its jet injector. (See Complaint, ¶¶18, 21, 28, 37, 42) In its Opposition to Defendant's

Rule 12(b)(6) Motion, Plaintiff begins with five pages detailing his understanding of the FDA approval process for a medical device and reiterates his conclusions regarding PharmaJet's failures to obtain necessary FDA approval for its medical device. Plaintiff concludes that Defendant's actions have left the FDA with few options to remedy the situation but contends that this Court can do what the FDA cannot, issue an injunction under the OCSPA to "compel PharmaJet to do medical monitoring on the thousands of potential plaintiffs who received flu shots with the PharmaJet injector, all without FDA approval...." See ECF #9 at p. 5. It seems clear that Plaintiff's claim is, in form and substance, one for violations of the FDCA.

The FDCA, however, does not provide a private right of action for violation of federal regulations. As set forth in the FDCA, the FDA has authority to enforce the regulations if it finds that a manufacturer has committed a violation. Specifically, Section 337(a) of the Act provides: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States**."** 21 U.S. C**.** § 337(a). It has been well settled by the Supreme Court and a host of federal Courts of Appeals and District Courts that § 337(a) is clear that there is no private right of action for violations of the FDCA. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions ..."); *Loreto v. Procter & Gamble Co.*, 737 F.Supp.2d 909, 918-19 (S.D. Ohio 2010); *Ellis v. C.R. Bard, Inc*., 311 F.3d 1272, 1284 n.10 (11th Cir. 2001); *Kemp v. Medtronic, Inc*., 231 F.3d 216, 236 (6th Cir. 2000); *In re Orthopedic Bone Screw Prods. Liab. Litig*., 193 F.3d 781, 788-89 (3d Cir. 1999).

Moreover, "[t]he absence of a private right of action to enforce the FDCA means not only

is a private party precluded from bringing suit to enforce the provisions of the FDCA, they also 'may not use other federal statutes or state unfair competition laws a**s a** vehicle to bring a private cause of action that is based on violations of the FDCA.'" *Loreto*, 737 F.Supp.2d at 919 (quoting *In re Epogen & Aransep Off-Label Mktg. & Sales Practices Litig.*, 590 F.Supp.2d 1282, 1290-91 (C.D. Cal. 2008)). Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp*., 625 F.Supp.2d 769, 777 (D. Minn. 2009). Plaintiff's claim would not exist if Defendant or someone else had submitted drug studies to the FDA and sought approval for the flu vaccine to be administered by jet injector. The crux of Plaintiff's claim is that Defendant violated FDA regulations and that purported violation forms the basis of Plaintiff's complaint. As such, the claim is barred by Section 337(a) and the well established case law interpreting it.

Plaintiff's citation to *Lohr v. Medtronic, Inc*., 518 U.S. 470 (1996) does not alter the fact that his claim is impliedly preempted under *Buckman*. In *Medtronic*, the Supreme Court held that the 510(k) clearance process for Class II medical devices did not impose device-specific requirements such that express preemption under § 360k of the Medical Device Amendments to the FDCA applied. *Id*. at 501. Thus, the Lohr's state law claims of negligent design, negligent manufacturing and failure to warn based upon an allegedly defective pacemaker lead received by Mrs. Lohr were not expressly pre-empted by § 360k. The *Medtronic* case did not involve implied preemption under § 337(a) as none of the Lohr's claims attempted to enforce the provisions of the FDCA or to assert a private cause of action based on violations of the FDCA.

However, as the Supreme Court made clear in *Buckman*, even if a state-law claim regarding a medical device is not expressly preempted by the FDCA, it may be impliedly preempted. *Buckman* was decided five years after *Medtronic* and the issue before the Court in *Buckman* was whether a private litigant may assert a cause of action for fraud on the FDA, arising from allegedly fraudulent representations made by the manufacturer's regulatory consultant to the FDA in the course of seeking pre-market approval exception for orthopedic bone screws. Plaintiffs claimed that had the representations not been made, the FDA would not have approved the devices and plaintiffs would not have been injured. In finding this claim to be impliedly preempted, the Supreme Court explicitly distinguished *Medtronic*:

> Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. See 518 U.S., at 481, 116 S.Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Buckman, 531 U.S. at 352-53. Similarly, this case falls squarely within the parameters of *Buckman* in that Plaintiff's claim exists solely on his belief that Defendant failed to complete the FDA's alleged Two phase approval process for the delivery and administration of the flu vaccine and rushed its device to market for gain and profit. The claim does not exist independently of the FDCA, and like the claims in *Buckman*, are impliedly preempted. Accordingly, Plaintiff's Complaint must be dismissed.

2. Does the Complaint State a Claim for Violation of the OCSPA?

Even if Plaintiff's claim were not impliedly preempted, Defendant asserts that the Complaint fails to assert the elements necessary to state a claim under the OCSPA. First, Defendant asserts that the Complaint fails to allege reliance or proximate cause. To establish a prima facie claim under the OCSPA, a plaintiff must "show a material misrepresentation, deceptive act or omission" that impacted his decision to purchase the item at issue. *Temple v. Fleetwood Enters., Inc.*, 133 Fed. Appx. 254, 265 (6th Cir. 2006) (citing *Mathias v. Am. Online, Inc.*, No. 79427, 2002 WL 377159, at *5 (Ohio Ct. App. Feb. 28, 2002) and *Janos v. Murduck*, 109 Ohio App.3d 583 (Ohio Ct. App. 1996)). "Whether it be termed an issue of reliance or an issue of proximate cause, an appropriate rule is that where the defendant is alleged to have made material representations or misstatements, there must be a cause and effect relationship between the defendant's acts and the plaintiff's injuries." *Lilly v. Hewlett-Packard Co.*, N. 05-cv-465, 2006 WL 1064063 at *5 (S.D. Ohio Apr. 21, 2006).

In this case, Plaintiff does not allege that he saw or was even aware of any alleged misrepresentations regarding the PharmaJet injector before or during the receipt of his flu shot. Rather, the Complaint makes clear that Plaintiff went to a Giant Eagle Pharmacy to obtain a flu shot for $25.00; that his attorney later confirmed that the Giant Eagle Pharmacy advertised that it offered "needle-free" injections; and, that the Pharmacy's health care provider administered a needle-free injection in Plaintiff's upper arm without asking Plaintiff if he would prefer a needle or needle-free injection. (Complaint, ¶¶6-8). The Complaint references statements allegedly appearing on Defendant's website regarding its injector and its uses. (Complaint, ¶¶ 11-12). However, it is clear that no representation made by Defendant on its website played any role in

convincing Plaintiff to obtain a flu shot with the PharmaJet injector. As such, the Complaint fails to allege the elements of reliance or proximate cause which are necessary to state a claim under the OCSPA.[2] Accordingly, Defendant's Motion to Dismiss the Complaint pursuant to Rule 12(b)(6) must be granted. Moreover, the Court finds that granting a motion to amend the Complaint would be futile in this instance because the essence of Plaintiff's current claim is an alleged violation of the FDCA for which there is no private cause of action. Moreover, the new potential claims suggested by Plaintiff involving negligent misrepresentation or fraud would fail for the same reason and there is also the problem that Plaintiff did not and cannot allege that PharmaJet made any misrepresentations to the Plaintiff, thus preventing the establishment of either potential new claim.[3]

CONCLUSION

For the reasons set forth above, Defendant's Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(6) (ECF #7) is GRANTED and this action will be dismissed. IT IS SO ORDERED.

/s/Donald C. Nugent
DONALD C. NUGENT
UNITED STATES DISTRICT JUDGE

DATED: February 3, 2012

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[2] In addition, Defendant argues that the Complaint fails to allege the necessary elements of a consumer transaction and that a consumer good was involved. PharmaJet's prescription medical device is not a good for personal, family or household use and thus is not a consumer good as defined by the OCSPA. Further, Defendant argues that there was no consumer transaction between PharmaJet and Plaintiff. Plaintiff's transaction was with the Giant Eagle Pharmacy and not with PharmaJet. Plaintiff purchased a flu vaccination from Giant Eagle, not a PharmaJet injector from Defendant. Plaintiff's complaint fails to state a claim for these additional reasons.

[3] As the Court has granted Plaintiff's Motion to Dismiss, it is unnecessary to rule on the Motion to Strike Class Allegations as the issue is moot. The entire action is dismissed.